REMARKS

Claims 34-37, 39, 41, 43, 44, and 71-73 as amended, remain herein. Claims 72 and 73 are new.

1. Claims 34-36, 39, 41, 43 and 44 were rejected under § 103(a) over Lyle '713 in view of Crocker '742. This is yet another restatement of the same issue alleged in prior Office Actions, but still no convincing rebuttal of applicants' traversing arguments has been presented in the Office Actions in this record.

Lyle '713 discloses a composition and method of therapeutic treatment for inhibiting vascular restenosis. Lyle, col. 4, lines 35-40, disclose administering in vivo an antisense polypeptide or oligonucleotide or molecule having similar specificity by using a balloon infusion catheter with holes in it for delivery to the particular target site to prevent life-threatening restenosis. This is the only description of a "balloon infusion catheter with holes in it" in Lyle '713. However, Lyle does not disclose a "seed" as that term is used in this application and widely in this art. Lyle '713 does not disclose a substantially hollow seed for implantation into a tissue or organ, which seed has an opening at each end thereof (or in the side wall as now specified in new dependent claims 72 and 73) for providing controlled diffusion of a therapeutic agent from such hollow seed. Nothing in Lyle '213 or in the Office Actions in this record shows such a seed.

There is no disclosure or teaching in Lyle '713 that would have suggested applicants' claimed invention to one of ordinary skill in this art. Nothing in the Office Action demonstrates that applicants' foregoing arguments distinguishing applicants' claims from Lyle, are incorrect.

Crocker '742 discloses a radiation delivery balloon for a balloon catheter that includes a central zone 32 and proximal zone 28. At an inflation pressure of about 8 atm., the proximal zone 28 has an outside diameter of about 3 mm and the central zone 32 has an outside diameter

of about 3.4 mm. As shown in Figs. 3 and 4, a large zone 32 is provided with a radiation source 34 surrounded by outer sleeve 38. Alternatively, the outer sleeve 38 can be omitted, and radiation source 34 adequately secured to the exterior of the balloon.

Crocker, like Lyle, does not disclose a "seed" as that term is used in this application and widely in this art. Crocker, like Lyle, does not disclose hollow seeds for implantation into a tissue or organ, which seeds have an opening at each end thereof (or the side wall as stated in new claims 72 and 73). The balloon catheters mentioned in both Lyle and Crocker are not seeds for implantation, and cannot be used as an implantable seed because it is necessary to have a central guide wire running through both ends of such balloons and secure them to the catheter. The Office Action of July 11, 2006 assumed that "such a wire would not preclude implantation," but did not explain any factual basis in either of the cited references (or any other logic) for such a conclusion. The January 29, 2007 Office Action retreated to saying "in the absence of the guide wire [the Crocker catheter] constitutes the claimed implantable seed." Again, no basis for this presumptive conclusionary leap is demonstrated in the Office Action or otherwise in this record.

The Office Action of January 29, 2007 further retreated saying that Crocker discloses "leaving the catheter in position for a sufficiently long time to deliver the desired dose of radiation after which the balloon is deflated and the catheter withdrawn. That is, the device is implanted, albeit temporarily." (Office Action, 1/29/07, pages 2-3). Admittedly, the balloon catheter remains in a patient's tissue only temporarily. That Office Action also argues that "the catheter and the guide wire are not of one piece." (id. at 2). One piece or not, the Crocker balloon portion is not a "seed" and is never left freestanding in the patient's body tissue.

The terms "consisting of," "seed," and "implementation" in applicants' claims have always meant, and mean in this art, a seed which when implanted is in a state of freestanding retention in a patient's body tissue – i.e., free from any catheter or other implantation device – so

that it can remain indefinitely *in situ*, in such tissue *in vivo*. Applicants' independent claim 34 expressly states that the claimed seed is adapted for implantation in tissue "and for freestanding retention therein indefinitely."

See the following definitions well known to those of ordinary skill in this art:

> The Free Dictionary
> Medical dictionary (see http://medical-dictionary.thefreedictionary.com/seed)
> Definition #2 for seed
> Seed: a small cylindrical shell of gold or other suitable material, used in application of radiation therapy.
>
> http://dictionary.reference.com/browse/seed (from Merriam-Webster's Medical Dictionary: half way down the webpage)
> Definition #2
> Seed: a small usually glass and golf or platinum capsule used as a container for a radioactive substance (as radium or radon) to be applied usually interstitially in the treatment of cancer <implementation of radon seeds for bladder cancer>.
>
> Wikipedia (http://en.wikipedia.org/wiki/Balloon_catheter)
> In contrast balloon catheter: A balloon catheter is a type of "soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body. The deflated balloon catheter is positioned, then inflated to perform the necessary procedure, and deflated again in order to be removed.

"Seed" is an art-recognized term which must be acknowledged as a limitation in applicants' claimed drug delivery device. A balloon catheter is not structurally or functionally the same as a seed.

MPEP 707.07(f), Examiner's form paragraph 7.37.09, in relevant part expressly states:

> [A] recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Here, (1) there is a structural difference between the claimed invention and the prior art (see definitions of seed vs. balloon catheter), and (2) the prior art structure is not capable of performing the intended use (a balloon catheter is not used for freestanding retention, see definition above).

One of ordinary skill in this art would readily distinguish between a balloon catheter and the instant seed invention, since both of these are art-known terms. The balloon catheter of the cited art can not perform the intended use "as a drug delivery device consisting of a substantially hollow seed. . . for freestanding retention therein indefinitely." Since the balloon catheter is not capable of performing the intended use and is structurally and functionally different from the instant invention, it can not render applicants' claims unpatentable.

Applicants' claimed seed is not a Lyle/Crocker style balloon catheter. There is nothing in either Lyle or Crocker that in any way suggests a hollow seed for freestanding, indefinite implantation, let alone such a seed for implantation having an opening at each end thereof, to provide controlled diffusion of a therapeutic agent from the hollow seed. And, contrary to the unsupported conclusion in the Office Action, there is nothing in Lyle or Crocker that would have made it obvious to use a balloon catheter as an implantation seed to be left indefinitely in a live body. Nor is there any disclosure or teaching in either Lyle or Crocker or anything else in this record that would have suggested the desirability of combining any portions thereof effectively to anticipate or suggest applicants' presently-claimed invention. Accordingly, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

2. Claim 71 was rejected under §112, first paragraph as allegedly not supported by an adequate written description. Claim 71 has been further amended and is now even more consistent with the written description at page 11, line 19 through page 12, line 1, of applicants' specification.

Reconsideration and withdrawal of this rejection are respectfully requested.

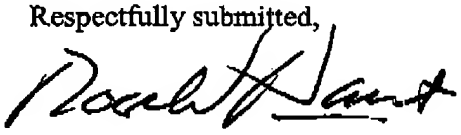
3. Claim 71 was rejected under §112, second paragraph, as indefinite. Claim 71 has been further amended for clarity, which should moot this rejection.

Reconsideration and withdrawal of this rejection are respectfully requested

For all the foregoing reasons, all claims 34-37, 39, 41, 43, 44, and 71-73 are now proper in form and patentably distinguished over all grounds of rejection cited in the Office Action. Accordingly, allowance of all claims is respectfully requested.

The PTO is hereby authorized to charge/credit any deficiency/overpayment to Deposit Account No. 19-4293 (Order No. 28964.0054). Should the Examiner believe that further changes would place this application in even better condition for issue, the Examiner is invited to telephone applicants' undersigned attorney.

Respectfully submitted,



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